

1 Jeffrey T. Bozman
2 COVINGTON & BURLING LLP
3 One CityCenter
4 850 Tenth Street, NW
5 Washington, DC 20001
6 Telephone: (202) 662-5829
7 Facsimile: (202) 778-5829
8 jbozman@cov.com

9 Attorney for Defendant
10 Eli Lilly and Company

11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION**

GILDA HAGAN-BROWN,

Plaintiff,

vs.

ELI LILLY AND COMPANY, an Indiana
corporation,

Defendant.

1:14-cv-01614-AJT-JFA

**ANSWER TO PLAINTIFF'S
COMPLAINT
DEMAND FOR JURY TRIAL**

Defendant Eli Lilly and Company ("Lilly"), by and through its undersigned attorney,
hereby files its Answer and Defenses to Plaintiff's Complaint.

INTRODUCTION

1. Lilly admits that it manufactures, markets, and sells Cymbalta®, for use only upon a prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings, precautions and other labeled risks and benefits of the medications. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the remaining allegations in Paragraph 1 and therefore denies the same.

1 **PARTIES**

2 2. Lilly lacks knowledge or information sufficient to form a belief as to the truth or
3 accuracy of the allegations in Paragraph 2 and therefore denies the same.

4 3. Lilly admits that it is an Indiana corporation with its principal place of business in
5 Indianapolis, Indiana. Lilly also admits that it is engaged in the business of research,
6 development, testing, manufacturing, producing, promoting, distributing, marketing, and selling
7 prescription medications, including but not limited to Cymbalta®. Lilly denies the remaining
8 allegations in Paragraph 3.

9 **JURISDICTION AND VENUE**

10 4. Lilly admits that this Court has subject matter jurisdiction in the form of diversity
11 jurisdiction.

12 5. Lilly admits that it is authorized to conduct business and does conduct business in
13 the Commonwealth of Virginia. Lilly denies the remaining allegations on the basis that they
14 purport to allege conclusions of law and thus do not require a response.

15 6. Paragraph 6 of the Complaint purports to allege conclusions of law and thus does
16 not require a response and on that basis Lilly denies the allegations.

17 7. Paragraph 7 purports to allege conclusions of law and thus does not require a
18 response and on that basis Lilly denies the allegations.

19 **FACTUAL ALLEGATIONS**

20 8. Paragraph 8 is vague and ambiguous as to time, content, and context and on that
21 basis, Lilly denies the allegations.

22 9. Lilly admits that it researched, tested, developed, manufactured, labeled, marketed
23 and sold Prozac®, for use only upon a prescription by a licensed physician, in accordance with
24 applicable laws and regulations, and for its approved indications with FDA-approved warnings,
25 precautions, and other labeled risks and benefits of the medication. Lilly admits that Prozac® is
26 in the class of prescription medications known as selective serotonin reuptake inhibitors
27 (“SSRIs”), but denies the relevance of the information. Lilly admits that the United States Food
28 and Drug Administration (“FDA”) approved Prozac® in 1987 as a safe and effective medication

1 for the treatment of Major Depressive Disorder (“MDD”). Lilly admits that Prozac®’s patent
2 expired in August 2001. Allegations pertaining to SSRIs as a class of antidepressants are vague
3 and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations.
4 Lilly denies the remaining allegations in Paragraph 9.

5 10. Lilly admits that Cymbalta® is a serotonin norepinephrine reuptake inhibitor
6 (“SNRI”). Allegations pertaining to statements made about SNRIs are vague and ambiguous as
7 to time, content, and context and on that basis, Lilly denies the allegations. Lilly denies the
8 remaining allegations in Paragraph 10.

9 11. Lilly denies the allegations in Paragraph 11.

10 12. Lilly admits that the FDA approved Cymbalta® in 2004 for the treatment of
11 Major Depressive Disorder (“MDD”). Lilly further admits that the FDA approved Cymbalta®
12 for the treatment of Generalized Anxiety Disorder (“GAD”) in 2007 and fibromyalgia in 2008.
13 Lilly denies the remaining factual allegations in Paragraph 12.

14 13. Lilly admits that the FDA approved Cymbalta® in 2004. Lilly also admits that it
15 researched, tested, developed, manufactured, labeled, marketed, and sold Cymbalta®, for use
16 only upon a prescription by a licensed physician, in accordance with applicable laws and
17 regulations, and for its approved indications with FDA-approved warnings, precautions, and
18 other labeled risks and benefits of the medication. Lilly further admits that it promoted
19 Cymbalta® to prescribers through its sales representatives. The allegations pertaining to the
20 promotion of Cymbalta® utilizing Lilly sales representatives are vague and ambiguous as to
21 time, content, and context and on that basis, Lilly denies the allegations. Lilly denies the
22 remaining allegations in Paragraph 13.

23 14. Lilly denies the allegations in Paragraph 14.

24 15. Lilly admits that the half-life of a drug is the time it takes for the concentration of
25 the drug in the body to be reduced by one-half. Lilly further admits that, since 2004, the
26 Cymbalta label has stated that the half-life of Cymbalta is approximately 12 hours. Lilly denies
27 the remaining allegations in Paragraph 15.
28

1 16. Lilly admits that Paragraph 16 contains an accurate partial quotation from the
2 2004 Cymbalta label. Lilly denies the remaining allegations in Paragraph 16 as characterized by
3 Plaintiff.

4 17. Lilly admits that the risk of discontinuation symptoms from antidepressant
5 therapy was a well understood clinical phenomenon for decades prior to Cymbalta's approval
6 and that the need for tapering off of antidepressant therapy was also well understood. Lilly
7 denies the remaining allegations in Paragraph 17.

8 18. Lilly denies the allegations in Paragraph 18. Answering further, Lilly notes that
9 the cited articles speak for themselves.

10 19. Lilly admits that Cymbalta is designed as delayed-release capsules at dosages of
11 20 mg, 30 mg, and 60 mg. Lilly further admits that Cymbalta should be swallowed whole. Lilly
12 denies the remaining allegations in Paragraph 19.

13 20. Lilly admits that the Cymbalta® label has included a warning on discontinuation
14 symptoms since Cymbalta® was approved by the FDA in 2004. Lilly admits that the
15 Cymbalta® label contains the following "WARNINGS AND PRECAUTIONS" section
16 regarding "Discontinuation of Treatment with Cymbalta®":

17 Discontinuation symptoms have been systematically evaluated in
18 patients taking duloxetine. Following abrupt or tapered
19 discontinuation in placebo-controlled clinical trials, the following
20 symptoms occurred at 1% or greater and at a significantly higher
21 rate in duloxetine-treated patients compared to those discontinuing
22 from placebo: dizziness, headache, nausea, diarrhea, paresthesia,
23 irritability, vomiting, insomnia, anxiety, hyperhidrosis, and fatigue.
24 During marketing of other SSRIs and SNRIs (serotonin and
25 norepinephrine reuptake inhibitors), there have been spontaneous
26 reports of adverse events occurring upon discontinuation of these
27 drugs, particularly when abrupt, including the following: dysphoric
28 mood, irritability, agitation, dizziness, sensory disturbances (e.g.,
paresthesias such as electric shock sensations), anxiety, confusion,
headache, lethargy, emotional lability, insomnia, hypomania,
tinnitus, and seizures. Although these events are generally self-
limiting, some have been reported to be severe.

Patients should be monitored for these symptoms when
discontinuing treatment with Cymbalta®. A gradual reduction in
the dose rather than abrupt cessation is recommended whenever
possible. If intolerable symptoms occur following a decrease in
the dose or upon discontinuation of treatment, then resuming the
previously prescribed dose may be considered. Subsequently, the

1 physician may continue decreasing the dose but at a more gradual
2 rate

3 Paragraph 20 is vague and ambiguous as to time, content, and context and on that basis, Lilly
4 denies the remaining allegations.

5 21. The article cited speaks for itself, and Lilly denies any inaccurate characterization
6 or interpretation of the article to which Plaintiff refers in Paragraph 21 of the Complaint when
7 read in context and in its entirety. Lilly denies the remaining allegations in Paragraph 21.

8 22. Paragraph 22 is vague and ambiguous as to time, content, and context and on that
9 basis, Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 22.

10 23. Lilly denies the allegations in Paragraph 23.

11 24. Lilly admits that Cymbalta is designed as delayed-release capsules at dosages of
12 20 mg, 30 mg, and 60 mg. Lilly further admits that Cymbalta should be swallowed whole. Lilly
13 denies the remaining allegations in Paragraph 24.

14 25. Lilly denies the allegations in Paragraph 25.

15 26. The allegations pertaining to the sales and profitability of Cymbalta are vague and
16 ambiguous as to time, content, and context and on that basis, Lilly denies the allegations. Lilly
17 denies the remaining allegations in Paragraph 26 as characterized by Plaintiff.

18 27. Lilly denies the allegations in Paragraph 27.

19 28. Lilly denies the allegations in Paragraph 28.

20 29. Lilly denies the allegations in Paragraph 29.

21 30. Paragraph 30 purports to allege conclusions of law and on that basis Lilly denies
22 the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to
23 the truth or accuracy of the allegations in Paragraph 30 relating to Plaintiff's use of Cymbalta
24 and therefore denies the same.

25 31. Lilly lacks knowledge or information sufficient to form a belief as to the truth or
26 accuracy of the allegations in Paragraph 31 pertaining to Plaintiff's Cymbalta prescription and
27 therefore denies the same. Lilly denies the remaining allegations in Paragraph 31.
28

1 32. Lilly lacks knowledge or information sufficient to form a belief as to the truth or
2 accuracy of the allegations in Paragraph 32 and therefore denies the same.

3 33. Lilly lacks knowledge or information sufficient to form a belief as to the truth or
4 accuracy of the allegations in Paragraph 33 pertaining to Plaintiff's alleged discontinuation
5 symptoms. Lilly denies the remaining allegations in Paragraph 33.

6 34. Lilly denies the allegations in Paragraph 34.

7 35. Lilly denies the allegations in Paragraph 35.

8 36. Paragraph 36 (a) - (e) purports to allege conclusions of law that do not require a
9 response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or
10 information sufficient to form a belief as to the truth or accuracy of the allegations relating to
11 Plaintiff's alleged injuries and therefore denies the same.

12 **FIRST CAUSE OF ACTION**

13 **NEGLIGENCE**

14 37. Lilly reincorporates and realleges its Responses to Paragraphs 1-36 of Plaintiff's
15 Complaint as if fully set forth herein.

16 38. Paragraph 38 purports to allege conclusions of law that do not require a response
17 and on that basis Lilly denies the allegations. Lilly further denies it had a duty to warn
18 consumers directly of alleged risks associated with the use of Cymbalta.

19 39. Paragraph 39 purports to allege conclusions of law that do not require a response
20 and on that basis Lilly denies the allegations. Lilly denies the remaining factual allegations in
21 Paragraph 39.

22 40. Paragraph 40 purports to allege conclusions of law that do not require a response
23 and on that basis Lilly denies the allegations. Lilly further denies the remaining factual
24 allegations in Paragraph 40.

25 41. Lilly denies the allegations in Paragraph 41. Moreover, Lilly lacks knowledge or
26 information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph
27 41 relating to Plaintiff's alleged injuries and therefore denies the same.

42. Paragraph 42 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 42 relating to Plaintiff's alleged injuries and therefore denies the same.

43. Lilly denies the allegations in Paragraph 43, except that Lilly admits only that Plaintiff seeks the relief set forth in Paragraph 43. Lilly denies that Plaintiff is entitled to any such relief.

SECOND CAUSE OF ACTION

DESIGN DEFECT

44. Lilly reincorporates and realleges its Responses to Paragraphs 1-43 of Plaintiff's Complaint as if fully set forth herein.

45. Lilly admits that it has sold Cymbalta in the Commonwealth of Virginia. Paragraph 45 is vague and ambiguous as to time and on that basis, Lilly denies the remaining allegations.

46. Lilly admits that it researched, tested, developed, manufactured, labeled, marketed, promoted, and sold Cymbalta, for use only upon a prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings, precautions, and other labeled risks and benefits of the medication. The remaining allegations pertaining to Lilly's "product" are vague and ambiguous as to time, content, and context, and on that basis, Lilly denies the allegations. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations and legal conclusions in Paragraph 46 relating to Plaintiff's alleged injuries from Cymbalta and therefore denies the same. Lilly denies the remaining allegations in Paragraph 46.

47. Lilly denies the allegations in Paragraph 47.

48. Lilly denies the allegations in Paragraph 48.

49. Lilly denies the allegations in Paragraph 49.

50. Paragraph 50 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, the allegations in Paragraph 50 are

1 vague and ambiguous as to time, content, and context, and on that basis, Lilly denies the
2 allegations.

3 51. Paragraph 51 purports to allege conclusions of law that do not require a response
4 and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information
5 sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 51 relating to
6 Plaintiff's alleged injuries and therefore denies the same.

7 52. Lilly denies the allegations in Paragraph 52, except that Lilly admits only that
8 Plaintiff seeks the relief set forth in Paragraph 52. Lilly denies that Plaintiff is entitled to any
9 such relief.

10 **THIRD CAUSE OF ACTION**

11 **FAILURE TO WARN**

12 53. Lilly reincorporates and realleges its Responses to Paragraphs 1-52 of Plaintiff's
13 Complaint as if fully set forth herein.

14 54. Lilly admits that it researched, tested, developed, manufactured, labeled,
15 distributed, marketed, promoted, and sold Cymbalta®, for use only upon a prescription by a
16 licensed physician, in accordance with applicable laws and regulations, and for its approved
17 indications with FDA-approved warnings, precautions, and other labeled risks and benefits of the
18 medication. Lilly further admits that it has utilized direct-to-consumer advertising for
19 Cymbalta®, in conformity with applicable rules and regulations. Lilly objects to the term
20 "persons responsible for consumers" as vague and ambiguous and on that basis denies the
21 allegation. Paragraph 54 further purports to allege conclusions of law that do not require a
22 response and on that basis Lilly denies the allegations. Lilly denies the remaining allegations in
23 Paragraph 54.

24 55. Paragraph 55 purports to allege conclusions of law that do not require a response
25 and on that basis Lilly denies the allegations.

26 56. Lilly admits that it had a duty to warn prescribing physicians about the known and
27 reasonably knowable risks associated with the use and discontinuation of Cymbalta®.
28

1 Answering further, Lilly denies it had a duty to warn consumers directly of alleged risks
2 associated with the use and discontinuation of Cymbalta®.

3 57. Plaintiff's allegation pertaining to "exclusive control" is vague and ambiguous as
4 to time, content, and context and on that basis, Lilly denies the allegation. Lilly denies the
5 remaining allegations in Paragraph 56.

6 58. Lilly denies the allegations in Paragraph 57.

7 59. Paragraph 58 purports to allege conclusions of law that do not require a response
8 and on that basis Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph
9 58.

10 60. Lilly denies the allegations in Paragraph 59.

11 61. Lilly lacks knowledge or information sufficient to form a belief as to the truth or
12 accuracy of the allegations in Paragraph 60 relating to Plaintiff's alleged use of Cymbalta® and
13 therefore denies the same.

14 62. Lilly lacks knowledge or information sufficient to form a belief as to the truth or
15 accuracy of the allegations relating to Plaintiff or Plaintiff's physician's ability to discover any
16 alleged "defect in the drug" and therefore denies the same. Lilly denies any remaining
17 allegations in Paragraph 61.

18 63. Lilly admits that it is engaged in the business of researching, developing, testing,
19 manufacturing, promoting, distributing, marketing, and selling prescription medications,
20 including but not limited to Cymbalta®. Paragraph 62 purports to allege conclusions of law that
21 do not require a response and on that basis, Lilly denies the allegations. Lilly denies the
22 remaining factual allegations in Paragraph 62.

23 64. Lilly lacks knowledge or information sufficient to form a belief as to the truth or
24 accuracy of the allegations in Paragraph 63 relating to Plaintiff's knowledge and therefore denies
25 the same. Lilly denies the remaining allegations in Paragraph 63.

26 65. Paragraph 64 purports to allege conclusions of law that do not require a response
27 and on that basis Lilly denies the allegations. Lilly denies the remaining factual allegations in
28 Paragraph 64.

1 66. Lilly denies the allegations in Paragraph 65.

2 67. Lilly denies the allegations in Paragraph 66.

3 68. Paragraph 67 purports to allege conclusions of law that do not require a response
4 and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information
5 sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 67 relating to
6 Plaintiff's alleged injuries and therefore denies the same.

7 69. Lilly denies the allegations in Paragraph 68, except that Lilly admits only that
8 Plaintiff seeks the relief set forth in Paragraph 68. Lilly denies that Plaintiff is entitled to any
9 such relief.

10 **FOURTH CAUSE OF ACTION**

11 **CONSTRUCTIVE FRAUD**

12 70. Lilly reincorporates and realleges its Responses to Paragraphs 1-68 of Plaintiff's
13 Complaint as if fully set forth herein.

14 71. Paragraph 70 purports to allege conclusions of law that do not require a response
15 and on that basis Lilly denies the allegations.

16 72. Lilly denies the allegations in Paragraph 71.

17 73. Paragraph 72 purports to allege conclusions of law that do not require a response
18 and on that basis Lilly denies the allegations. Lilly denies the remaining factual allegations.

19 74. Lilly denies the allegations in Paragraph 73.

20 75. Lilly denies the allegations in Paragraph 74. Moreover, Lilly lacks knowledge or
21 information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph
22 74 relating to Plaintiff and/or her physicians' alleged actions, knowledge, beliefs, and injuries
23 and therefore denies the same.

24 76. Paragraph 75 purports to allege conclusions of law that do not require a response
25 and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information
26 sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 75 and
27 therefore denies the same.

28

1 77. Paragraph 76 purports to allege conclusions of law that do not require a response
2 and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information
3 sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 76 relating to
4 Plaintiff's alleged injuries and therefore denies the same.

5 78. Lilly denies the allegations in Paragraph 77, except that Lilly admits only that
6 Plaintiff seeks the relief set forth in Paragraph 77. Lilly denies that Plaintiff is entitled to any
7 such relief.

8 **FIFTH CAUSE OF ACTION**

9 **ACTUAL FRAUD**

10 79. Lilly reincorporates and realleges its Responses to Paragraphs 1-77 of Plaintiff's
11 Complaint as if fully set forth herein.

12 80. Paragraph 79 purports to allege conclusions of law that do not require a response
13 and on that basis Lilly denies the allegations. Answering further, Lilly notes that the text of
14 *Wyeth v. Levine*, 555 U.S. 555, 571 (2009), speaks for itself.

15 81. Lilly denies the allegations in Paragraph 80.

16 82. Lilly denies the allegations in Paragraph 81.

17 83. Lilly denies the allegations in Paragraph 82 (a) - (i).

18 84. Lilly denies the allegations in Paragraph 83.

19 85. Paragraph 84 purports to allege conclusions of law that do not require a response
20 and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information
21 sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 84 and
22 therefore denies the same.

23 86. Paragraph 85 purports to allege conclusions of law that do not require a response
24 and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information
25 sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 85 and
26 therefore denies the same.

27 87. Lilly denies the allegations in Paragraph 86.

1 88. Paragraph 87 purports to allege conclusions of law that do not require a response
2 and on that basis Lilly denies the allegations.

3 89. Lilly denies the allegations in Paragraph 88.

4 90. Paragraph 89 purports to allege conclusions of law that do not require a response
5 and on that basis Lilly denies the allegations. Lilly further denies the remaining allegations in
6 Paragraph 89.

7 91. Paragraph 90 purports to allege conclusions of law that do not require a response
8 and on that basis Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph
9 90, except that Lilly admits only that Plaintiff seeks the relief set forth in Paragraph 90. Lilly
10 denies that Plaintiff is entitled to any such relief.

11 92. Paragraph 91 purports to allege conclusions of law that do not require a response
12 and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information
13 sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 91 relating to
14 Plaintiff's alleged injuries and therefore denies the same.

15 **SIXTH CAUSE OF ACTION**

16 **BREACH OF IMPLIED WARRANTY**

17 93. Lilly reincorporates and realleges its Responses to Paragraphs 1-91 of Plaintiff's
18 Complaint as if fully set forth herein.

19 94. Lilly denies the allegations in Paragraph 93.

20 95. Paragraph 94 purports to allege conclusions of law that do not require a response
21 and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information
22 sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 94 relating to
23 Plaintiff's alleged injuries or Plaintiff's alleged "use and discontinuation" of Cymbalta® and
24 therefore denies the same.

25 96. Lilly lacks knowledge or information sufficient to form a belief as to the truth or
26 accuracy of the allegations in Paragraph 95 and therefore denies the same.

27 97. Paragraph 96 purports to allege conclusions of law that do not require a response
28 and on that basis Lilly denies the allegations. Lilly denies the remaining factual allegations.

1 98. Paragraph 97 purports to allege conclusions of law that do not require a response
2 and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information
3 sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 97 relating to
4 Plaintiff's injuries and therefore denies the same.

5 99. Paragraph 98 purports to allege conclusions of law that do not require a response
6 and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information
7 sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 98 relating to
8 Plaintiff's alleged injuries and therefore denies the same. Answering further, Lilly denies the
9 remaining allegations in Paragraph 99, except that Lilly admits only that Plaintiff seeks the relief
10 set forth in Paragraph 99. Lilly denies that Plaintiff is entitled to any such relief.

11 100. Lilly denies each and every allegation in Plaintiff's Complaint not specifically
12 admitted herein.

13 **PRAYER FOR RELIEF**

14 Lilly denies the allegations in this section of Plaintiff's Complaint, except that Lilly
15 admits only that Plaintiff seeks the relief set forth in this section. Lilly denies that Plaintiff is
16 entitled to any relief whatsoever.

17 **DEMAND FOR JURY TRIAL**

18 This section of Plaintiff's Complaint does not assert any allegation requiring a response.
19 To the extent a response is deemed necessary, Lilly admits that Plaintiff requests a trial by jury.

20 **GENERAL DENIAL AND DEFENSES**

21 Discovery and investigation may reveal that any one or more of the following defenses
22 should be available to Lilly in this matter. Lilly, therefore, asserts said defenses in order to
23 preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Lilly
24 may withdraw any of these defenses as may be appropriate. Further, Lilly reserves the right to
25 amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims
26 and defenses as discovery proceeds. Further answering and by way of additional defense, Lilly
27 states the following:
28

1 **FIRST DEFENSE**

2 Each and every claim asserted or raised in the Complaint is barred by the applicable
3 statute of limitations and is otherwise untimely.

4 **SECOND DEFENSE**

5 The Complaint fails to state a claim upon which relief can be granted.

6 **THIRD DEFENSE**

7 Each and every claim asserted or raised in the Complaint is barred by the doctrines of
8 estoppel, waiver or statutory and regulatory compliance.

9 **FOURTH DEFENSE**

10 If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information
11 and belief, such injuries or losses were caused in whole or in part through the operation of nature
12 or other intervening or superseding cause or causes.

13 **FIFTH DEFENSE**

14 To the extent that Plaintiff asserts claims based upon an alleged failure by Lilly to warn
15 Plaintiff directly of alleged dangers associated with the use of Cymbalta®, such claims are
16 barred under the learned intermediary doctrine because Lilly has discharged its duty to warn in
17 its warnings to the prescribing physician.

18 **SIXTH DEFENSE**

19 To the extent that Plaintiff asserts claims based on Lilly's adherence to and compliance
20 with applicable state laws, regulations and rules, such claims are preempted by federal law under
21 the Supremacy Clause of the United States Constitution.

22 **SEVENTH DEFENSE**

23 Plaintiff has not sustained an ascertainable loss of property or money.

24 **EIGHTH DEFENSE**

25 In the unlikely event that liability is established by Plaintiff in this case, any liability that
26 might otherwise be imposed upon this Defendant is subject to a defense of contributory
27 negligence. *See Ponirakis v. Choi*, 262 Va. 119, 124 (2001); *Artrip v. E.E. Berry Equipment Co.*,
28 240 Va. 354, 358 (1990).

1 **NINTH DEFENSE**

2 If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or
3 losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk
4 of any injury as the result of the consumption of, administration of, or exposure to any medicine
5 or pharmaceutical preparation manufactured or distributed by Lilly or other manufacturer.

6 **TENTH DEFENSE**

7 If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information
8 and belief, such injuries and losses were caused by the actions of persons not having real or
9 apparent authority to take said actions on behalf of Lilly and over whom Lilly had not control
10 and for whom Lilly may not be held accountable.

11 **ELEVENTH DEFENSE**

12 If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information
13 and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of
14 Cymbalta®.

15 **TWELFTH DEFENSE**

16 If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or
17 losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or
18 environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical
19 conditions or natural course of conditions for which this Defendant is not responsible.

20 **THIRTEENTH DEFENSE**

21 To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are
22 also barred for lack of timely notice of breach and/or lack of privity.

23 **FOURTEENTH DEFENSE**

24 Plaintiff's claims are barred, in whole or in part, because Plaintiff did not rely on any act,
25 omission, or representation made by Lilly.

26 **FIFTEENTH DEFENSE**

1 To the extent that Plaintiff seeks punitive damages for the conduct which allegedly
2 caused the injuries asserted in the Complaint, such an award would, if granted, violate Lilly's
3 state and federal rights.

4 **SIXTEENTH DEFENSE**

5 No act or omission of Lilly was willful, wanton, reckless or grossly negligent and,
6 therefore, any award of punitive damages is barred.

7 **SEVENTEENTH DEFENSE**

8 Plaintiff has not suffered any actual injury or damages.

9 **EIGHTEENTH DEFENSE**

10 Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the
11 Restatement (Second) of Torts.

12 **NINETEENTH DEFENSE**

13 Plaintiff's claims are barred in whole or in part because Lilly provided legally adequate
14 "directions or warnings" as to the use of Cymbalta® and any other medicine or pharmaceutical
15 preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of
16 the Restatement of (Second) of Torts.

17 **TWENTIETH DEFENSE**

18 Plaintiff's claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts:
19 Products Liability.

20 **TWENTY-FIRST DEFENSE**

21 Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of
22 Torts: Products Liability.

23 **TWENTY-SECOND DEFENSE**

24 There is no practical or technically feasible alternative design that would have reduced
25 the alleged risk without substantially impairing the reasonably anticipated and intended function
26 of Cymbalta®. Plaintiff's causes of action are barred in whole or in part by their failure to assert
27 a safer design for Cymbalta.
28

1 **TWENTY-THIRD DEFENSE**

2 Plaintiff's claims are barred in whole or in part by failure to mitigate damages.

3 **TWENTY-FOURTH DEFENSE**

4 Plaintiff's claims are barred in whole or in part because Lilly's conduct conforms with
5 medical knowledge.

6 **TWENTY-FIFTH DEFENSE**

7 With respect to each and every cause of action, Plaintiff is not entitled to recover for
8 strict liability because Plaintiff cannot state claims founded in strict liability because, among
9 other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates
10 Plaintiff's claims to a negligence cause of action.

11 **TWENTY-SIXTH DEFENSE**

12 With respect to each and every cause of action, Plaintiff is not entitled to recover because
13 if the product involved was unsafe, which Lilly denies, then it was unavoidably unsafe as defined
14 in the Restatement of Torts. The apparent benefits of the product exceeded any apparent risk
15 given the scientific knowledge available when the product was marketed.

16 **TWENTY-SEVENTH DEFENSE**

17 Lilly's advertisement and labeling with respect to the products which are the subject
18 matter of this action were not false or misleading and, therefore, constitute protected commercial
19 speech under the applicable provisions of the United States and Virginia Constitutions.

20 **TWENTY-EIGHTH DEFENSE**

21 The public interest in the benefit and availability of the product which is the subject
22 matter of this action precludes liability for risks, if any, resulting from any activities undertaken
23 by Defendant, which were unavoidable given the state of human knowledge at the time those
24 activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk
25 inherent in the product which is the subject matter of this action, then such risk, if any, is
26 outweighed by the benefit of the product.

27 **TWENTY-NINTH DEFENSE**

1 Lilly made no warranties of any kind, express or implied, including any alleged implied
2 warranty of merchantability or any representations of any nature whatsoever to the Plaintiff.

3 **THIRTIETH DEFENSE**

4 At all times relevant herein, any product which is the subject matter of this action
5 manufactured and distributed by Lilly in any state in the United States was manufactured and
6 distributed in a reasonable and prudent manner based upon available medical and scientific
7 knowledge and further was processed and distributed in accordance with and pursuant to all
8 applicable regulations of the FDA.

9 **THIRTY-FIRST DEFENSE**

10 With respect to each and every purported cause of action, the acts of Lilly were at all
11 times done in good faith and without malice.

12 **THIRTY-SECOND DEFENSE**

13 To the extent there were any risks associated with the use of the product which is the
14 subject matter of this action which Lilly knew or should have known and which gave rise to a
15 duty to warn, Lilly at all times discharged such duty through appropriate and adequate warnings
16 in accordance with federal and state law.

17 **THIRTY-THIRD DEFENSE**

18 Plaintiff's claims against Lilly are barred because Plaintiff's treating physicians fully
19 informed Plaintiff of the risks associated with the use of Cymbalta. Any informed consent
20 and/or release given by Plaintiff is pleaded as an affirmative defense.

21 **THIRTY-FOURTH DEFENSE**

22 To the extent Plaintiff's claims are based on alleged misrepresentations made to the FDA,
23 such claims are barred pursuant to Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341
24 (2000).

25 **THIRTY-FIFTH DEFENSE**

26 Plaintiff's claims for pre-judgment and post-judgment interest are limited by the dates
27 and amounts set forth in Va. Code 1950 § 8.01-382

28 **THIRTY-SIXTH DEFENSE**

1 Plaintiff's damages claims are barred by the economic loss doctrine.

2 **THIRTY-SEVENTH DEFENSE**

3 Plaintiff's claims of fraud are barred by reason of the Complaint's failure to allege the
4 factual circumstances constituting the alleged fraud with particularity.

5 **THIRTY-EIGHTH DEFENSE**

6 Plaintiff's claims are barred in whole, or in part, because the product at all times relevant
7 hereto complied with all applicable laws and regulations to which the product was in any respect
8 subject, including but not limited to the deference that the common law gives to discretionary
9 action by the Food and Drug Administration.

10 **THIRTY-NINTH DEFENSE**

11 Plaintiff's claims may be barred by failure to join indispensable parties.

12 **FORTIETH DEFENSE**

13 Any claims relating to alleged communications with regulatory agencies of the U.S.
14 government are barred in whole or in part by operation of Lilly's First Amendment right to
15 petition the government (the *Noerr-Pennington* Doctrine).

16 **FORTY-FIRST DEFENSE**

17 To the extent Plaintiff asserts demand for punitive damages, Lilly specifically
18 incorporates by reference any and all standards of limitations regarding the determination and/or
19 enforceability of punitive damages awards that arose in the decisions of *BMW of No. America v.*
20 *Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S.
21 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003); and *Exxon*
22 *Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their
23 progeny as well as other similar cases under both federal and state law.

24 **FORTY-SECOND DEFENSE**

25 Any claim for punitive damages requires proof of actual or express malice. *See Cook v.*
26 *Patterson Drug Co.*, 185 Va. 516, 522 (1946).

27 **FORTY-THIRD DEFENSE**

1 To the extent that Plaintiff asserts a claim for punitive damages, that claim is in
2 contravention of the rights of Lilly under the following constitutional provisions:

3 a. Plaintiff's claim for punitive damages violates, and is therefore barred by, the
4 Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the
5 United States of America, and the analogous provisions of the Virginia
6 Constitution, on grounds including the following:

- 7 i. the procedures pursuant to which punitive damages are awarded fail to
8 provide specific standards for the amount of the award of punitive
9 damages which thereby violates the Due Process Clause of the Fourteenth
10 Amendment of the United States Constitution, and the analogous
11 provisions of the Virginia Constitution;
- 12 ii. the procedures pursuant to which punitive damages are awarded result in
13 the imposition of different penalties for the same or similar acts, and thus
14 violate the Equal Protection Clause of the Fourteenth Amendment of the
15 United States Constitution, and the analogous provisions of the Virginia
16 Constitution;
- 17 iii. the procedures pursuant to which punitive damages are awarded permit the
18 imposition of punitive damages in excess of the maximum criminal fine
19 for the same or similar conduct, which thereby infringes upon the Due
20 Process Clause of the Fifth and Fourteenth Amendments and the Equal
21 Protection Clause of the Fourteenth Amendment of the United States
22 Constitution, and the analogous provisions of the Virginia Constitution;
- 23 iv. the procedures pursuant to which punitive damages are awarded permit the
24 imposition of excessive fines in violation of the Eighth Amendment of the
25 United States Constitution, and the analogous provisions of the Virginia
26 Constitution;
- 27 v. the award of punitive damages to Plaintiff in this action would constitute a
28 deprivation of property without due process of law; and

1 vi. the procedures pursuant to which punitive damages are awarded permit the
2 imposition of an excessive fine and penalty.

3
4 **FORTY-FORTH DEFENSE**

5 Any claim for punitive damages is limited by Va. Code § 8.01-38.1 and shall not exceed
6 \$350,000. Lilly asserts all other defenses and limitations on punitive damages contained in Va.
7 Code § 8.01-38.1.

8 **FORTY-FIFTH DEFENSE**

9 Plaintiff's claims are barred, in whole or in part, because Cymbalta® was designed,
10 manufactured, distributed, marketed, and labeled with proper warnings, information, cautions,
11 and instructions, in accordance with the state of the art and the state of scientific and
12 technological knowledge. Lilly invokes all state of the art defenses applicable to Plaintiff's
13 claims, including the state of the art applicable to the industry in question, medicine, medical
14 science, and all others, alleging that it discharged, according to law and due care, each and every
15 duty which Plaintiff may have been owed.

16 Inasmuch as the Complaint does not describe the alleged underlying claims with
17 sufficient particularity to enable Lilly to determine all of its legal, contractual, and equitable
18 rights, Lilly reserves the right to amend and/or supplement the averments of its Answer to assert
19 any and all pertinent liability defenses ascertained through further investigation and discovery.

20 Lilly will rely on all defenses that may become available during discovery or trial.

21 WHEREFORE, Lilly respectfully demands judgment dismissing the Complaint with
22 prejudice and awarding Lilly its reasonable costs and disbursements, including reasonable
23 attorneys' fees, together with such and other and further relief that the court may deem just and
24 proper.

25 **JURY DEMAND**

26 Lilly demands a trial by jury as to all issues triable.

27 DATED this 5th day of January 2015.
28

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

By: /s/ Jeffrey T. Bozman
Jeffrey T. Bozman

Attorney for Defendant
ELI LILLY AND COMPANY

CERTIFICATE OF SERVICE

I hereby certify that on the 5th day of January, 2015, I will electronically file the foregoing with the Clerk of Court using the CM/ECF system, which will then send a notification of such filing (NEF) to the following:

Peter A. Miller
Miller Legal LLC
175 S. Pantops Drive, Third Floor
Charlottesville, VA 22911
Tel: (434) 529-6909
Fax: (888) 830-1488
Email: PMiller@MillerLegalLLC.com
Counsel for Gilda Hagan-Brown

/s/
Jeffrey Todd Bozman (VA 83679)
Covington & Burling LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
Tel: (202) 662-5829
Fax: (202) 778-5829
jbozman@cov.com
Counsel for Eli Lilly and Company